Focus Report

New Chemicals Program

PMN Number: **L-14-0403**

Focus Date:	07/21/2014	Report Status:	Completed
Consolidated Set:			
Focus Chair:	Jeff Bauer	Contractor:	Olga Svetlitskaya

I. Notice Information

Submitter:	Resman USA	CAS Number:	[redacted]
Chemical Name:	[redacted]		
Use:	Tracer for production monitoring in oil and gas wells. [redacted] CRSS: forward. P2 Claims: The LVE substance can replace radioactive, high volume chemical, or fluorinated tracers.		
Other Uses:	[redacted] .		
PV-Max:	200 Kg/yr	Binding Option:	Awaiting ISIS Entry
Manufacture:		Import:	X

II. SAT Results

(1) **Health Rating:** 1 **Eco Rating:** 1 **Comments:** ;

Occupational:	**Non-Occupational:**	**Environmental:**
(1) **PBT:** 1 1	1 Awaiting Human Health Entry Awaiting Human Health Entry Awaiting Human Health Entry	**Comments:**

III. OTHER FACTORS

Categories:

Health Chemical Category:		Ecotox SAR and TSCA New Chemical Category:	anionic surfactants; Anionic Surfactants

Related Cases/Regulatory History:

Health related Cases:	
Ecotox Related Cases:	Analogs: [redacted]
Regulatory History:	[redacted] - GRANTED WITH CONDITION (CG) [redacted] - GRANTED
CRSS P2Rec:	P2Rec-P2 Recognition

MSDS/Label Information:

MSDS:

Exposure Based Information:

Exposure Based Review:	N	Exposure Based Review (Health):	
Exposure Based Review (Eco):	N	Exposure Based (Occupational):	No
Exposure Based Review (Non Occupatuional):		Exposure Based (Environmental):	

IV. Summary of SAT Assessment

Fate:

Fate Summary:

L-14-0402-03
FATE: [redacted]
Solid
S > 10 g/L at 25 °C (E)
VP < 1.0E-6 torr at 25 C (E)
BP > 400 C (E)
H < 1.00E-8 (E)
POTW removal (%) = 50-90 via sorption and biodeg; L-14-0402: ISO TC/147/SC5/WG4, N141(Marine BODIS): 7%/28d; L-14-0403: OECD 306(Seawater, Closed Btl): 3%/28d.
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = moderate
PBT Potential: P1B1
*CEB FATE: Migration to ground water = moderate

Health:

Health Summary:

Not absorbed through the skin, moderate absorption from the GI tract; good absorption from the lung (analog). No significant health concerns.

Ecotox:

Ecotox Values:

Fish 96-h LC50:	>100(P)	> 100(M)
Daphnid 48-h LC50:	>100(P)	> 100(M)
Green algal 96-h EC50:	>100(P)	> 100(M)
Fish Chronic Value:	>10(P)	
Daphnid ChV:	>10(P)	
Algal ChV:	>10(P)	> 10(M)

Ecotox values comments:

Predictions are based on SARs for anionic surfactants; SAR chemical class = surfactant-anionic-[redacted]; S = 890/240 g/L at 20 C (P); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <150.0 mg/L as CaCO3; and TOC <2.0 mg/L;

Ecotoxicity Test Data Results for L-14-0403: [redacted] Trade name: RGTW-04-01).

A marine fish, two marine invertebrate, and a marine algae toxicity studies were completed for PMN L-14-0403in 2014 by Opus Maxim Limited, Norway for Resman USA. The PMN material is described as a solid in the neat form, [redacted] The PMN substance has an estimated water solubility of 243 g/L and Log Kow of -6.66, and Henry's Law Constant of < 1.00 x 10-8 atm-m3/mole for the representative structure. This PMN is expected to be water soluble and nonvolatile. The PMN material is used as a tracer for production monitoring in oil and gas wells. The acute marine fish study was reported to follow OECD 203 (Acute Toxicity for Fish) as adapted by OSPAR Commission (2006) Part B: Protocol for a fish acute toxicity test. The acute marine invertebrate studies were reported to follow the test methods of ISO 14669 (1999) Water quality – Determination of acute lethal toxicity to marine copepods (Copepoda Crustacea), ISO 5667-16 (1998) Water Quality Sampling – Guidance on Biotesting of Samples, and OSPAR Commission guidelines (2006) Part A: A sediment Bioassay Using an Amphipod Corophium sp.). The acute marine algae study was reported to follow ISO 10253 (2006) Water Quality – Marine Algal Growth Inhibition Test with Skeletonema costatum. All studies were conducted under GLP conditions.

Fish Ecotoxicity Test:
Opus Maxim Limited conducted a 96-hour limit test in the sheepshead minnow (Cyprinodon variegatus) with L-14-0403 (purity not specified) under semi-static conditions with renewal after 48 hours. This study was reported to follow OECD test guideline No. 203 (1992), as adapted by OSPAR Commission 2006 Part B for marine testing of offshore chemicals. Single replicates of ten C. variegatus were exposed to a dilution water control (UV treated seawater) or the test substance

at a nominal concentration of 2262.2 mg/L. No analytical measurement or verification of the test concentrations was completed. To prepare the test solution, an appropriate amount of test substance was directly added to seawater, since the test substance was observed to be soluble prior to testing. The tests were conducted in 5 L glass beakers containing 3 L of test media. The preparations were mixed in situ to ensure thorough dissolution before introduction of the test organisms. The pH was adjusted to 6 - 9 and gentle aeration was supplied to all tanks. During the study, temperature ranged from 18.9 - 21.2 °C, pH ranged from 7.98 - 8.15, dissolved oxygen ranged from 96.4 - 100.4 % and salinity ranged from 33.4 - 34.9 ‰. No mortalities or effects were observed for any replicate. There was no clear reporting of the test substance composition and purity and concentrations in the test vessels were not verified; however, this test is considered to be adequate. Based on nominal concentrations, the 96-hour LC50 is > 2262.2 mg/L.
96-hour LC50 > 2262.2 mg/L

Invertebrate Ecotoxicity Test:
(1) Opus Maxim Limited conducted a 48-hour sediment bioassay in marine amphipods (Acartia tonsa) with L-14-0403 (purity not specified). This study was reported to follow ISO guideline No. 14669 (1999) and ISO guideline No. 5667-16 (1998). Following a range-finding study, two replicates of ten A. tonsa were exposed to the test substance at nominal concentrations of 1000, 1800, 3200, 5600 and 10,000 mg/L. Four control (UV sterilized seawater) replicates were tested concurrently. No analytical measurement or verification of the test concentrations was completed. Tests were conducted in 100 mL capacity glass dishes each containing 50 mL of test medium covered with soda glass watch covers. To prepare the test solution, the appropriate weight of test material was added to treated seawater to prepare an initial stock since the substance was considered to be soluble in seawater. Appropriate volumes were taken from this stock to prepare subsequent test concentrations which were brought to volume with culture medium. During the study, temperature ranged from 17.9 - 19.1 °C and dissolved oxygen ranged from 89.1 - 96.0 % (8.49 - 9.13 at 48h). At the start of the study, the pH ranged from 7.90 - 8.44 in the test and control solutions. The salinity of the dilution water was 36 ‰. A loading rate of 200 copepods/L was calculated. The % mortality at 0, 1000, 1800, 3200, 5600 and 10,000 mg/L was 5.3 %, 21 %, 40 %, 78 %, 100 %, and 100 %, respectively. There was no clear reporting of the test substance composition and purity and concentrations in the test vessels were not verified; however, this test is considered to be adequate. Based on nominal concentrations, the 48-hour LC50 was 2262.2 mg/L.
48-hour LC50 = 2262.2 mg/L

(2) Opus Maxim Limited conducted a 10-day sediment bioassay in marine amphipods (Corophium volutator) with L-14-0403 (purity not specified). Test methods were conducted in accordance with OSPARCOM guidelines 2006 Part A. Three replicates of twenty C. volutator were exposed to the test substance at target wet weight concentrations 10, 100, 320, 1000 and 10,000 mg/kg. Corresponding nominal dry weight concentrations of 14.16, 141.82, 453.86, 1418.2 and 14183.51 mg/kg were calculated using a wet-to-dry sediment ratio of 1.42. Concentrations of the PMN in the sediment were not analytically verified. Additionally, five control replicates of twenty C. volutator were tested concurrently. The sediment was field collected and wet-sieved through 0.6 mm mesh to remove larger infaunal organisms. The sediment was characterized as a fine sand with a silt/clay content of 31.6 % by weight and median particle diameter was 100 µm. The organic material content was estimated to be 2 %. Immediately before test initiation, the sediment was homogenized and the ratio of wet weight to dry weight was determined. Tests were conducted in 1 L capacity glass beakers each containing 2 cm depth (approximately 150 mL) of amended sediment and 850 mL of overlying seawater (1 µm filtered ultra violet treated seawater). To prepare the test medium, an appropriate amount of test substance was dissolved in a small quantity of seawater and added directly to the mixing container containing wet sediment. The mixing vessels were then placed on a platform shaker at approximately 150 rpm for 3 hours. After this period, the contents of each container were equally distributed between the replicate vessels. Vessels were covered with a sheet of Perspex perforated with a small hole above the center of each beaker. Aeration was provided and a stream of air bubbles was released at a depth of approximately 6 cm. The observed mortality data for the treatments was not provided in the report. Over the course of the study, temperature ranged from 14.1 - 14.8 °C, pH ranged from 8.09 - 8.17, dissolved oxygen ranged from 86 – 102 % and salinity ranged from 36 - 44 ‰. Based on nominal concentrations, the 10-day LC50 was > 14184 mg/kg dry weight. The test concentrations should have been analytically determined throughout the test period, the mortality data should have been reported, and there was no clear reporting of the test substance however, this test was considered to be adequate.

10-day LC50 > 14184 mg/kg dry weight

Algal Ecotoxicity Test:
Opus Maxim Limited conducted a 72-hour algal growth inhibition toxicity test in marine algae (Skeletonema costatum) with L-14-0403 (purity not specified) under static conditions. This study was reported to follow ISO guideline No. 10253 (2006) and ISO guideline No. 5667-16 (1998). Following a range-finding study, three replicates of S. costatum (10,000 cells/mL) were exposed to the test substance at nominal concentrations of 100, 320, 1000, 3200 and 10,000 mg/L. Six control replicates were tested concurrently with ISO culture medium only. No analytical measurement or verification of the test concentrations was completed. The light intensity during the study ranged from 6150 - 8800 lux in the controls. Tests were conducted in 100 mL capacity glass flasks to which 50 mL of test medium seawater was added. Following inoculation, all flasks were loosely covered with aluminum foil caps and mounted on an orbital shaker at approximately 150 rpm. To prepare the test solution, an appropriate weight of test material was added to culture medium to prepare an initial stock. Appropriate volumes were taken from this stock to prepare subsequent test concentrations which were brought to volume with culture medium. During the study, temperature ranged from 19.4 - 20.9 °C. At the start of the study, the pH ranged from 7.99 - 8.01 in the test and control solutions. Salinity of the dilution medium was 36 – 37 ‰. There was no clear reporting of the test substance composition and purity and concentrations in the test vessels were not verified; however, this test is considered to be adequate. Based on nominal concentrations, the 72-hour EC50 for growth rate was 9992.43 mg/L. The 72-hour NOEC and LOEC values were 3200 and 10,000 mg/L, respectively. A ChV of 5656.9 mg/L was calculated.
72-hour EC50 (growth rate) = 9992.43 mg/L
72-hour NOEC = 3200 mg/L
72-hour LOEC = 10,000 mg/L
72-hour ChV = 5656.9 mg/L

The 96-hour marine fish toxicity test (LC50 > 2262.2 mg/L), the 48-hour marine amphipod water column invertebrate toxicity test (LC50 = 2262.2 mg/L), the 10-day marine amphipod invertebrate sediment toxicity test (LC50 > 14,184 mg/kg sediment dry weight), and 72-hour marine algae (EC50 = 9992.43 mg/L; NOEC = 3200 mg/L; LOEC = 10,000 mg/L) were adequate for L-14-0403. For comparative purposes, the 96-hour fish LC50 of > 100 mg/L, the 48-hour daphnid LC50 of > 100 mg/L, the 96-hour algae EC50 of > 100 mg/L, and the fish, daphnid, and algae chronic values (ChV) of > 10 mg/L were calculated based on SARs for anionic surfactants. Based on the acute marine amphipod experimental data of 2262.2 mg/L (2,262,200 ppb), and the application of an assessment factor of 5, the acute concentration of concern (CoC) for L-14-0403 is 452,440 ppb. The marine copepod experimental results indicate that it is the most sensitive species, thus the chronic value (ChV) for P-14-0403 is calculated by dividing the marine copepod LC50 of 2262.2 mg/L by an acute to chronic ratio of 10 to yield a ChV of 226.22 mg/L (226,220 ppb). The chronic CoC for P-14-0403 is then derived by dividing the ChV of 226.22 mg/L (226,220 ppb) by a factor of 10 (assessment factor) yielding a chronic CoC of 22,622 ppb.

Acute CoC = 452,440 ppb
Chronic CoC = 22,622 ppb

Ecotox Study Reviewer: K. Eisenreich July 11, 2014

Ecotox Factors:

Assessment Factor:	10
Concern Concentration: - Acute Value	
Concern Concentration: - Chronic Value	1000

V. Summary of Exposures/Releases

Engineering Summary:

Exposures/Releases			
Scenario			
Sites			
Media			
Descriptor A			
Quantity A (kg/site/day)			
Frequency A (day/year)			
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From			
Workers			
Exposure Type			

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: LVE Grant Decision Date: 07/21/2014
Type of Decision:

Rationale: L-14-0403 was granted. Human health hazard concerns were low. Ecotoxicity hazard concerns were low based on ecotoxicity data submitted on the LVE and SAR for anionic surfactants. This LVE was not bound at 200 kg/yr and was assessed at 10,000 kg/yr. This was a CEB D1 Drop and an EAB Drop. The P2REC was forwarded.

P2 Rec Comments:

Testing:

Final Recommended:

Health:
Eco:
Fate:
Other:

SAT Report

PMN Number: **L-14-0403**
SAT Date: **7/8/2014**
Print Date: **12/4/2015**

Related cases: [redacted]

Health related cases:
Ecotox related cases: Analogs: [redacted]

Concern levels:

Type of Concern:	**Health**	**Eco**	**Comments**
Level of Concern:	1	1	

Persistence	**Bioaccum**	**Toxicity**	**Comments**
1	1	1 Awaiting Human Health Entry Awaiting Human Health Entry Awaiting Human Health Entry	

Exposure Based Review:

Health:
Ecotox: No

Routes of exposure:

Health: No exposures needed
Ecotox: No releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: L-14-0402-03

FATE: [redacted]
Solid
S > 10 g/L at 25 °C (E)
VP < 1.0E-6 torr at 25 C (E)

BP > 400 C (E)
H < 1.00E-8 (E)
POTW removal (%) = 50-90 via sorption and biodeg; L-14-0402: ISO TC/147/SC5/WG4, N141(Marine BODIS): 7%/28d; L-14-0403: OECD 306(Seawater, Closed Btl): 3%/28d.
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = moderate
PBT Potential: P1B1
*CEB FATE: Migration to ground water = moderate

Health:

Health Summary: Not absorbed through the skin, moderate absorption from the GI tract; good absorption from the lung (analog). No significant health concerns.

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	>100	> 100	LC50 > 2262; marine
daphnid	**48-h**	**LC50**	>100	> 100	EC50 = 2262; marine
green algal	**96-h**	**EC50**	>100	> 100	EC50 = 9992; marine
fish	**_**	**chronic value**	>10		
daphnid	**_**	**chronic value**	>10		
algal	**_**	**chronic value**	>10	> 10	ChV = 5657; marine
Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

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medium. During the study, temperature ranged from 17.9 - 19.1 °C and dissolved oxygen ranged from 89.1 - 96.0 % (8.49 - 9.13 at 48h). At the start of the study, the pH ranged from 7.90 - 8.44 in the test and control solutions. The salinity of the dilution water was 36 ‰. A loading rate of 200 copepods/L was calculated. The % mortality at 0, 1000, 1800, 3200, 5600 and 10,000 mg/L was 5.3 %, 21 %, 40 %, 78 %, 100 %, and 100 %, respectively. There was no clear reporting of the test substance composition and purity and concentrations in the test vessels were not verified; however, this test is considered to be adequate. Based on nominal concentrations, the 48-hour LC50 was 2262.2 mg/L.
48-hour LC50 = 2262.2 mg/L

(2) Opus Maxim Limited conducted a 10-day sediment bioassay in marine amphipods (Corophium volutator) with L-14-0403 (purity not specified). Test methods were conducted in accordance with OSPARCOM guidelines 2006 Part A. Three replicates of twenty C. volutator were exposed to the test substance at target wet weight concentrations 10, 100, 320, 1000 and 10,000 mg/kg. Corresponding nominal dry weight concentrations of 14.16, 141.82, 453.86, 1418.2 and 14183.51 mg/kg were calculated using a wet-to-dry sediment ratio of 1.42. Concentrations of the PMN in the sediment were not analytically verified. Additionally, five control replicates of twenty C. volutator were tested concurrently. The sediment was field collected and wet-sieved through 0.6 mm mesh to remove larger infaunal organisms. The sediment was characterized as a fine sand with a silt/clay content of 31.6 % by weight and median particle diameter was 100 µm. The organic material content was estimated to be 2 %. Immediately before test initiation, the sediment was homogenized and the ratio of wet weight to dry weight was determined. Tests were conducted in 1 L capacity glass beakers each containing 2 cm depth (approximately 150 mL) of amended sediment and 850 mL of overlying seawater (1 µm filtered ultra violet treated seawater). To prepare the test medium, an appropriate amount of test substance was dissolved in a small quantity of seawater and added directly to the mixing container containing wet sediment. The mixing vessels were then placed on a platform shaker at approximately 150 rpm for 3 hours. After this period, the contents of each container were equally distributed between the replicate vessels. Vessels were covered with a sheet of Perspex perforated with a small hole above the center of each beaker. Aeration was provided and a stream of air bubbles was released at a depth of approximately 6 cm. The observed mortality data for the treatments was not provided in the report. Over the course of the study, temperature ranged from 14.1 - 14.8 °C, pH ranged from 8.09 - 8.17, dissolved oxygen ranged from 86 – 102 % and salinity ranged from 36 - 44 ‰. Based on nominal concentrations, the 10-day LC50 was > 14184 mg/kg dry weight. The test concentrations should have been analytically determined throughout the test period, the mortality data should have been reported, and there was no clear reporting of the test substance however, this test was considered to be adequate.
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measurement or verification of the test concentrations was completed. The light intensity during the study ranged from 6150 - 8800 lux in the controls. Tests were conducted in 100 mL capacity glass flasks to which 50 mL of test medium seawater was added. Following inoculation, all flasks were loosely covered with aluminum foil caps and mounted on an orbital shaker at approximately 150 rpm. To prepare the test solution, an appropriate weight of test material was added to culture medium to prepare an initial stock. Appropriate volumes were taken from this stock to prepare subsequent test concentrations which were brought to volume with culture medium. During the study, temperature ranged from 19.4 - 20.9 °C. At the start of the study, the pH ranged from 7.99 - 8.01 in the test and control solutions. Salinity of the dilution medium was 36 – 37 ‰. There was no clear reporting of the test substance composition and purity and concentrations in the test vessels were not verified; however, this test is considered to be adequate. Based on nominal concentrations, the 72-hour EC50 for growth rate was 9992.43 mg/L. The 72-hour NOEC and LOEC values were 3200 and 10,000 mg/L, respectively. A ChV of 5656.9 mg/L was calculated.
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72-hour NOEC = 3200 mg/L
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Acute CoC = 452,440 ppb
Chronic CoC = 22,622 ppb

Ecotox Study Reviewer: K. Eisenreich July 11, 2014

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb)		

Acute		
Concentration of Concern (ppb) Chronic	1000	
SARs	anionic surfactants	
SAR Class	surfactant-anionic-[redacted]	
TSCA New Chemcial Category	Anionic Surfactants	

Ecotox Factors Comments:

SAT Chair: L Keifer 564-8916
Fate assessor: Ecotox assessor: Health assessor: